PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
1778PCT:PJW:JWH:AML		
International Application No.	International Filing Date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/AU00/00792	30 June 2000	1 July 1999

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] A61K 47/44, 47/42, 47/38, 47/36, 47/26; A61P 3/02

Applicant

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
4 January 2001	24 July 2001
Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**STEVEN CHEW** Telephone No. (02) 6283 2248

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU00/00792

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **1-28,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **29-34,** received on **6 July 2001** with the letter of 5 July 2001

☒ the drawings, pages **1/3-3/3,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-61	YES
	Claims	NO
Inventive step (IS)	Claims 1-61	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-61	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

NOVELTY (N), INVENTIVE STEP (IS): Claims 1-61

The invention defined by claims 1-61 is directed to an enteral formulation for nasogastric delivery comprising:

(a) an amino acid source

(b) a carbohydrate source

(c) a lipid source and

(d) a fatty acid delivery agent, being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid, wherein the formulation can be delivered through a feeding tube.

The cited art of WO 95/13801 discloses a formulation including the same fatty acid delivery agent administered by oral ingestion. However there is no teaching or suggestion that the formulation can be delivered through a feeding tube. Therefore claims 1-61 are novel and have an inventive step.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of I

Rule 67 lists the subject matter which under Article 34(4)(a)(i) an international preliminary examination is not required to be carried out. At item (iv) it specifies methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods, as such matter. However the agreement between WIPO and Australia further qualifies this by excepting from exclusion any subject matter which is examined under national grant procedures. Claims 39-61 have nonetheless been considered because the identified subject matter does not contravene Australian law.

CLAIMS

1. An enteral formulation for nasogastric delivery including,
   a) an amino acid source
   b) a carbohydrate source,
   c) a lipid source, and
   d) a fatty acid delivery agent, being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid, wherein the formulation can be delivered through a feeding tube so as to release sufficient fatty acid in the colon to give rise to a health benefit to a recipient.

2. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation has a viscosity of no more than about 40cP at 25°C.

3. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation has a viscosity of no more than about 20cP at 25°C.

4. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation is capable of being stored for at least 24 hours and not forming a gel or precipitate that is not easily resuspended.

5. An enteral formulation for nasogastric delivery as in claim 1 wherein the enteral formulation is also an elemental formulation and includes a mineral source and a vitamin source.

6. An enteral formulation for nasogastric delivery as in claim 1 wherein the fatty acid is a short chain fatty acid (SCFA).

7. An enteral formulation for nasogastric delivery as in claim 6 wherein the SCFA is selected from the group consisting of, acetate, propionate, butryate, caproate, isovalerate, valerate and branched or modified derivatives thereof.

8. An enteral formulation for nasogastric delivery as in claim 6 wherein the SCFA is acetate.

9. An enteral formulation for nasogastric delivery as in claim 6 wherein the SCFA is propionate.

10. An enteral formulation for nasogastric delivery as in claim 6 wherein the SCFA is butyrate.

11. An enteral formulation for nasogastric delivery as in claim 1 wherein the fatty acid is a SCFA or an omega 3 fatty acid, an omega 6 fatty acid or stearadonic acid.

12. An enteral formulation for nasogastric delivery as in claim 11 wherein the omega 3 fatty acid is selected from the group consisting of linolenic acid, eicosapentaenoic acid, docosahexaenoic acid, and the omega 6 fatty acid is linoleic acid.

13. An enteral formulation for nasogastric delivery as in claim 1 wherein the carrier is a carbohydrate.

14. An enteral formulation for nasogastric delivery as in claim 13 wherein the carrier is water soluble.

15. An enteral formulation for nasogastric delivery as in claim 14 wherein the carrier is a soluble non-starch polysaccharide.

16. An enteral formulation for nasogastric delivery as in claim 15 wherein the soluble non-starch polysaccharide is selected from the group consisting of inulin, pectin, chitin, β glucans, mucilages, agar, carageenans, alginates and gums.

17. An enteral formulation for nasogastric delivery as in claim 15 wherein the carbohydrate is a pectin selected from the group consisting of high, medium and low methoxylated pectins and high, medium and low gel strength pectins and pectins derived from oranges, lemons or apples.

18. An enteral formulation for nasogastric delivery as in claim 15 wherein the carbohydrate is a gum selected from the group consisting of, guar, arabic, xantham, tragacanth, locust bean and psyllium.

19. An enteral formulation for nasogastric delivery as in claim 13 wherein the carrier is an insoluble non-starch polysaccharide.

20. An enteral formulation for nasogastric delivery as in claim 19 wherein the insoluble non-starch polysaccharide is selected from the group consisting of cellulose and hemicellulose.

21. An enteral formulation for nasogastric delivery as in claim 20 wherein the cellulose is selected from the group consisting of celluloses derived from oat hull, soybeans and cereal bran, microcrystalline celluloses, methyl celluloses, hydroxypropylmethyl cellulose and carboxymethylcellulose.

22. An enteral formulation for nasogastric delivery as in claim 13 wherein the carbohydrate is an oligosaccharide selected from the group consisting of fructooligosaccharides, galactooligosaccharides, short chain amylodextrins and maltodextrins and modifications and derivatives thereof.

23. An enteral formulation for nasogastric delivery as in claim 13 wherein the carbohydrate is a starch.

24. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is a starch digestible in the small intestine.

25. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is a starch resistant to digestion in the small intestine.

26. An enteral formulation for nasogastric delivery as in claim 25 wherein the starch is a high amylose starch.

27. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is a native starch.

28. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is a modified starch.

29. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is modified through the use of any one or more of the following, heat and/or moisture, physically, enzymatically, chemical hydrolysis, esterification, oxidation, cross bonding with difunctional reagents, and carboxymethylation.

30. An enteral formulation for nasogastric delivery as in claim 1 wherein the bond is selected from the group consisting of an ester bond, and ether bond or an amide bond.

31. An enteral formulation for nasogastric delivery as in claim 23 wherein the agent is made from an aqueous acylation method.

32. An enteral formulation for nasogastric delivery as in claim 23 wherein the degree of substitution ranges from 0.05 acyl group per saccharide unit to 2 acyl groups per saccharide unit.

33. An enteral formulation for nasogastric delivery as in claim 23 wherein the degree of substitution ranges from 0.1 acyl groups per saccharide unit to 0.5 acyl group per saccharide unit.

34. An enteral formulation for nasogastric delivery as in claim 6 wherein the carrier is a starch and the formulation having by weight 0.25% to about 5% of the fatty acid delivery agent.

35. An enteral formulation for nasogastric delivery as in claim 6 wherein the carrier is a starch and the formulation having by weight 0.5% to about 4% of the fatty acid delivery agent.

36. An enteral formulation for nasogastric delivery as in claim 6 wherein the carrier is a starch and the formulation having by weight about 2% of the fatty acid delivery agent.

37. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation is a preprepared in liquid form.

38. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation is dry requiring addition of water and agitation to form a suspension ready for use.

39. A method of elevating the level of SCFA in the colon of a human or animal, including the step of delivering a fatty delivery agent in a physiologically acceptable medium through a feeding tube to elevate the level of SCFA, the fatty acid delivery agent being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid.

40. The method of claim 39 wherein the physiological acceptable medium is an enteral feed formulation, including,
    a) an amino acid source,
    b) a carbohydrate source, and
    c) a lipid source.

41. The method of claim 39 wherein the fatty acid is a SCFA.

42. The method of claim 41 wherein the carrier is a starch.

43. The method of claim 39 wherein the level of the fatty acid within the large bowel increases within a time period of 6 hrs.

44. The method of claim 39 wherein the level of the SCFA within the large bowel increases within a time period of 4 hrs.

45. The method of claim 39 wherein the level of the fatty acid within the large bowel increases within a time period of 2 hrs.

46. The method of claim 39 wherein the fatty acid delivery agent constitutes less than about 30% by weight of the formulation.

47. The method of claim 39 wherein the fatty acid delivery agent constitutes less than about 20% by weight of the formulation.

48. The method of claim 39 wherein the fatty acid delivery agent constitutes less than about 10% by weight of the formulation.

49. The method of claim 39 wherein the fatty acid delivery agent constitutes less than about 5% by weight of the formulation.

50. A method of elevating the level of SCFA in the colon of a human or animal, including the step of delivering a fatty delivery agent in an enteral formulation to elevate the level of SCFA within the colon,
    the enteral formulation including
    a) an amino acid source,
    b) a carbohydrate source and
    c) a lipid source, and

d) a fatty acid delivery agent being a short chain fatty acid covalently bonded to a starch molecule by a bond hydrolysable in the colon to there by release the fatty acid.

51. The method of claim 50 wherein the enteral formulation is delivered through a nasogastric tube.

52. The method of claim 51 wherein the starch is a resistant starch.

53. The method of claim 52 wherein the resistant starch is a high amylose starch.

54. The method of claim 53 wherein the SCFA is selected from the group consisting of acetate, propionate and butyrate.

55. The method of claim 54 wherein the quantity of fatty acid delivery agent delivered is between 5 and 80gm/day.

56. The method of claim 54 wherein the quantity of fatty acid delivery agent delivered is between about 10 and 60 g/day.

57. The method of claim 54 wherein the quantity of fatty acid delivery agent delivered is between about 40 g/day.

58. The method of claim 55 wherein no more than 2 litres of the enteral formulation is delivered within a 24 hour time period.

59. The method of claim 55 wherein no more than 1 litre of the enteral formulation is delivered within a 24 hour time period.

60. The method of claim 55 wherein the fatty acid delivery agent is present in the formulation between 0.25% and about 5% by weight of the formulation.

61. The method of claim 55 wherein the fatty acid delivery agent is present in the formulation at about 2% by weight of the formulation.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00792

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61K 47/44, 47/42, 47/36, 47/38, 47/26; A61P 3/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K 47/- AND KEY WORDS AS SET OUT BELOW

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC AS ABOVE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT: FATTY ACIDS, CARBOHYDRATE, STARCH, CELLULOSE, LIPID AND RELATED TERMS.
MEDLINE:

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95/13801 A (COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION), 26 May 1995 page 8 line 8 -page 9 line 32; page 11 line 1-17	1-61
A	EP 451750 A (NB INTERNATIONAL TECHNOLOGIES), 16 October 1991 whole document	1-61
A	US 5723446 A (GRAY et al.) 3 March 1998 Whole document	1-61

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 July 2000	8 AUG 2000
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	S. CHEW Telephone No : (02) 6283 2248

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00792

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	9513801	AU	81368/94	CA	2176719	EP	730447
		US	5840860				
EP	451750	AU	74050/91	CA	2039980	JP	5306222
		US	5919822				
US	5723446	NONE					

END OF ANNEX

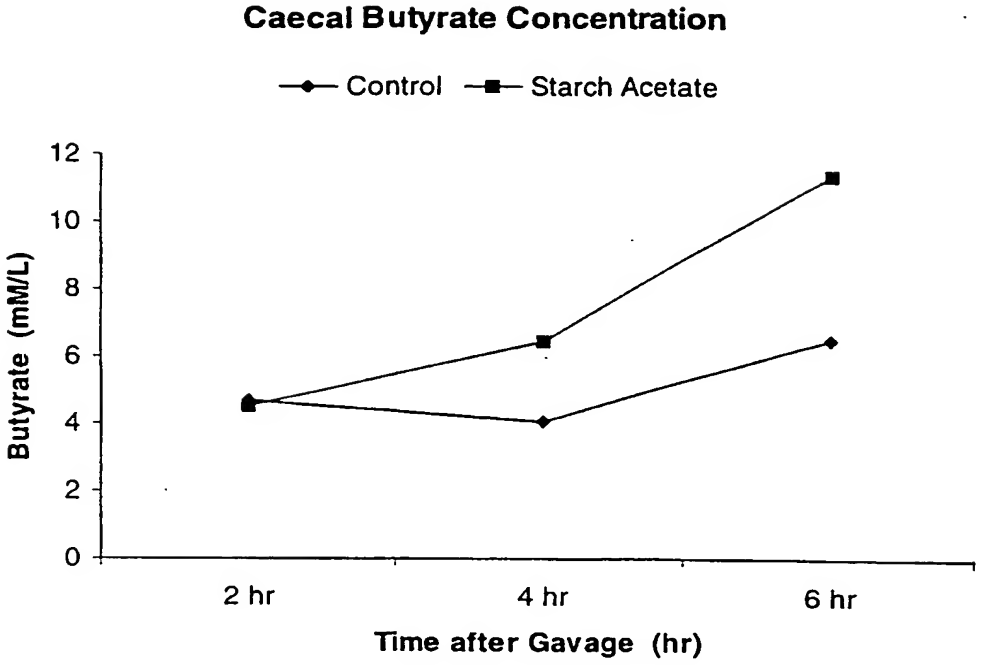

FIGURE 1

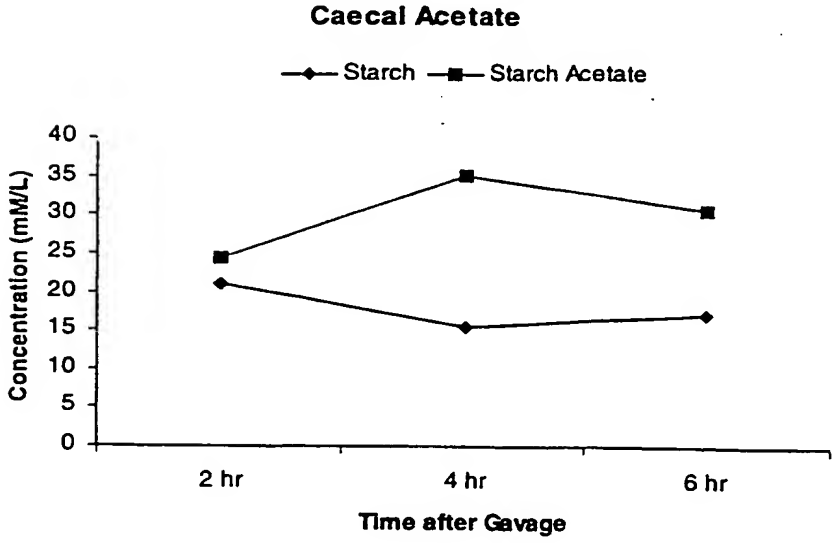

FIGURE 2

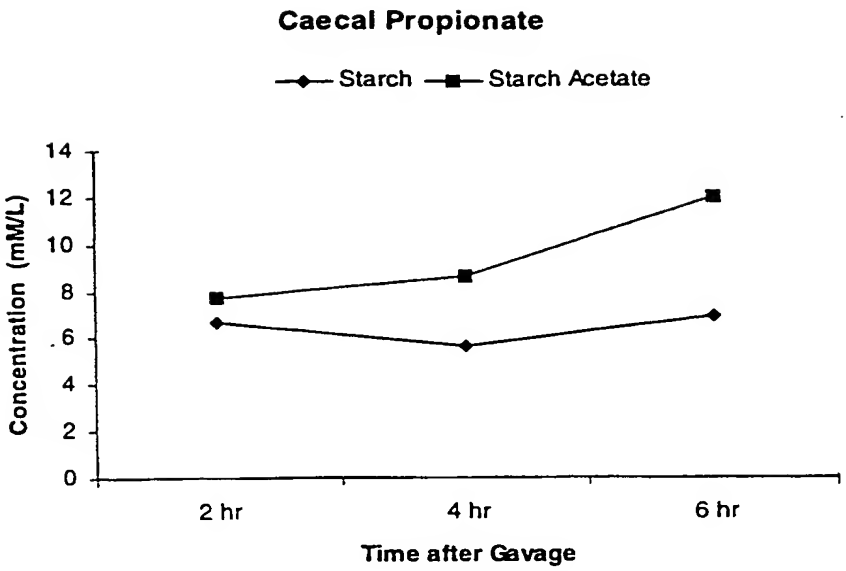

FIGURE 3

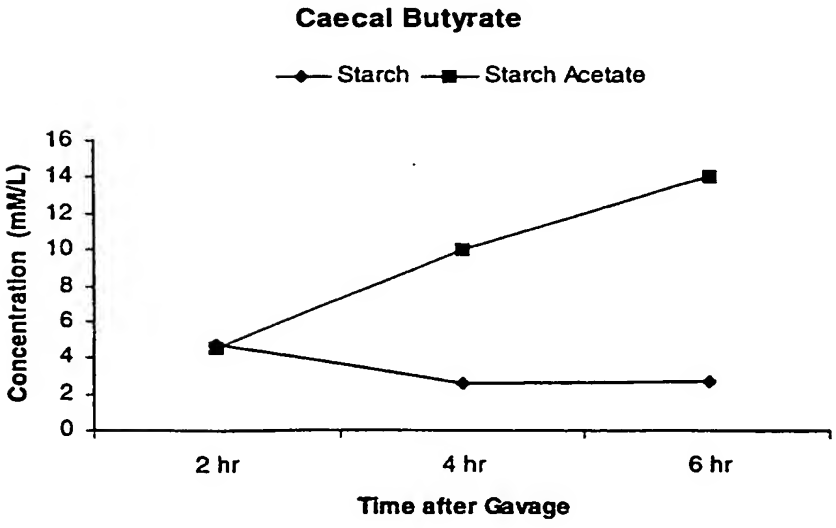

FIGURE 4

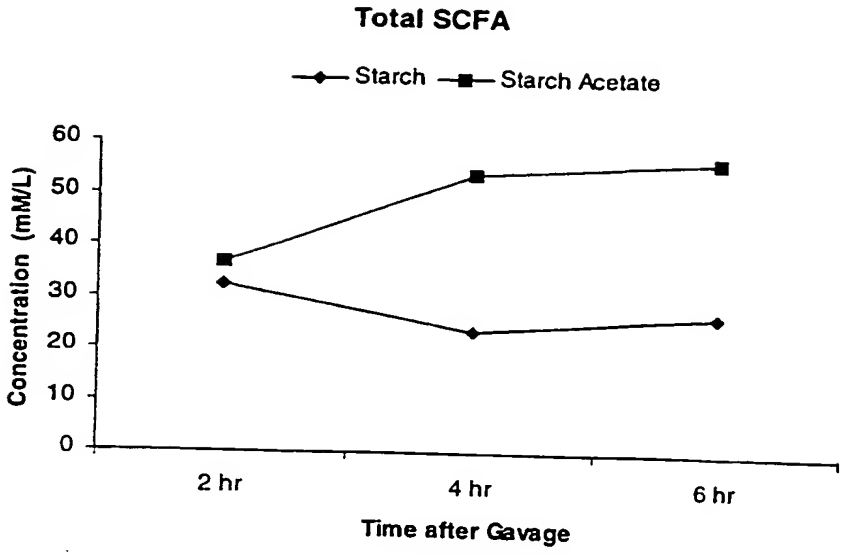
Total SCFA
Starch
Starch Acetate
Concentration (mM/L)
60
50
40
30
20
10
0
2 hr
4 hr
6 hr
Time after Gavage

FIGURE 5

14

REC'D 01 AUG 2001
WIPO PCT

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1778PCT:PJW:JWH:AML	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU00/00792**	International Filing Date *(day/month/year)* 30 June 2000	Priority Date *(day/month/year)* 1 July 1999
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] A61K 47/44, 47/42, 47/38, 47/36, 47/26; A61P 3/02		
Applicant COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION et al		

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VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand 4 January 2001	Date of completion of the report 24 July 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **STEVEN CHEW** Telephone No. (02) 6283 2248

INTERNATIONAL PRELIMIN[redacted]EXAMINATION REPORT

I[redacted]ational application No.
PCT/AU00/00792

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

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pages , filed with the demand,
pages , received on with the letter of

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **29-34,** received on **6 July 2001** with the letter of 5 July 2001

☒ the drawings, pages **1/3-3/3,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	**1-61**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-61**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-61**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

NOVELTY (N), INVENTIVE STEP (IS): Claims 1-61

The invention defined by claims 1-61 is directed to an enteral formulation for nasogastric delivery comprising:

(a) an amino acid source

(b) a carbohydrate source

(c) a lipid source and

(d) a fatty acid delivery agent, being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid, wherein the formulation can be delivered through a feeding tube.

The cited art of WO 95/13801 discloses a formulation including the same fatty acid delivery agent administered by oral ingestion. However there is no teaching or suggestion that the formulation can be delivered through a feeding tube. Therefore claims 1-61 are novel and have an inventive step.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

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CLAIMS

1. An enteral formulation for nasogastric delivery including,
   a) an amino acid source
   b) a carbohydrate source,
   c) a lipid source, and
   d) a fatty acid delivery agent, being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid.

2. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation has a viscosity of no more than about 40cP at 25°C.

3. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation has a viscosity of no more than about 20cP at 25°C.

4. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation is capable of being stored for at least 24 hours and not forming a gel or precipitate that is not easily resuspended.

5. An enteral formulation for nasogastric delivery as in claim 1 wherein the enteral formulation is also an elemental formulation and includes a mineral source and a vitamin source.

6. An enteral formulation for nasogastric delivery as in claim 1 wherein the fatty acid is a short chain fatty acid (SCFA).

7. An enteral formulation for nasogastric delivery as in claim 6 wherein the SCFA is selected from the group consisting of, acetate, propionate, butryate, caproate, isovalerate, valerate and branched or modified derivatives thereof.

8. An enteral formulation for nasogastric delivery as in claim 6 wherein the SCFA is acetate.

9. An enteral formulation for nasogastric delivery as in claim 6 wherein the SCFA is propionate.

10. An enteral formulation for nasogastric delivery as in claim 6 wherein the SCFA is butyrate.

11. An enteral formulation for nasogastric delivery as in claim 1 wherein the fatty acid is a SCFA or an omega 3 fatty acid, an omega 6 fatty acid or stearadonic acid.

12. An enteral formulation for nasogastric delivery as in claim 11 wherein the omega 3 fatty acid is selected from the group consisting of linolenic acid, eicosapentaenoic acid, docosahexaenoic acid, and the omega 6 fatty acid is linoleic acid.

13. An enteral formulation for nasogastric delivery as in claim 1 wherein the carrier is a carbohydrate.

14. An enteral formulation for nasogastric delivery as in claim 13 wherein the carrier is water soluble.

15. An enteral formulation for nasogastric delivery as in claim 14 wherein the carrier is a soluble non-starch polysaccharide.

16. An enteral formulation for nasogastric delivery as in claim 15 wherein the soluble non-starch polysaccharide is selected from the group consisting of inulin, pectin, chitin, β glucans, mucilages, agar, carageenans, alginates and gums.

17. An enteral formulation for nasogastric delivery as in claim 15 wherein the carbohydrate is a pectin selected from the group consisting of high, medium and low methoxylated pectins and high, medium and low gel strength pectins and pectins derived from oranges, lemons or apples.

18. An enteral formulation for nasogastric delivery as in claim 15 wherein the carbohydrate is a gum selected from the group consisting of, guar, arabic, xantham, tragacanth, locust bean and psyllium.

19. An enteral formulation for nasogastric delivery as in claim 13 wherein the carrier is an insoluble non-starch polysaccharide.

20. An enteral formulation for nasogastric delivery as in claim 19 wherein the insoluble non-starch polysaccharide is selected from the group consisting of cellulose and hemicellulose.

21. An enteral formulation for nasogastric delivery as in claim 20 wherein the cellulose is selected from the group consisting of celluloses derived from oat hull, soybeans and cereal bran, microcrystalline celluloses, methyl celluloses, hydroxypropylmethyl cellulose and carboxymethylcellulose.

22. An enteral formulation for nasogastric delivery as in claim 13 wherein the carbohydrate is an oligosaccharide selected from the group consisting of fructooligosaccharides, galactooligosaccharides, short chain amylodextrins and maltodextrins and modifications and derivatives thereof.

23. An enteral formulation for nasogastric delivery as in claim 13 wherein the carbohydrate is a starch.

24. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is a starch digestible in the small intestine.

25. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is a starch resistant to digestion in the small intestine.

26. An enteral formulation for nasogastric delivery as in claim 25 wherein the starch is a high amylose starch.

27. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is a native starch.

28. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is a modified starch.

29. An enteral formulation for nasogastric delivery as in claim 23 wherein the starch is modified through the use of any one or more of the following, heat and/or moisture, physically, enzymatically, chemical hydrolysis, esterification, oxidation, cross bonding with difunctional reagents, and carboxymethylation.

30. An enteral formulation for nasogastric delivery as in claim 1 wherein the bond is selected from the group consisting of an ester bond, and ether bond or an amide bond.

31. An enteral formulation for nasogastric delivery as in claim 23 wherein the agent is made from an aqueous acylation method.

32. An enteral formulation for nasogastric delivery as in claim 23 wherein the degree of substitution ranges from 0.05 acyl group per saccharide unit to 2 acyl groups per saccharide unit.

33. An enteral formulation for nasogastric delivery as in claim 23 wherein the degree of substitution ranges from 0.1 acyl groups per saccharide unit to 0.5 acyl group per saccharide unit.

34. An enteral formulation for nasogastric delivery as in claim 6 wherein the carrier is a starch and the formulation having by weight 0.25% to about 5% of the fatty acid delivery agent.

35. An enteral formulation for nasogastric delivery as in claim 6 wherein the carrier is a starch and the formulation having by weight 0.5% to about 4% of the fatty acid delivery agent.

36. An enteral formulation for nasogastric delivery as in claim 6 wherein the carrier is a starch and the formulation having by weight about 2% of the fatty acid delivery agent.

37. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation is a preprepared in liquid form.

38. An enteral formulation for nasogastric delivery as in claim 1 wherein the formulation is dry requiring addition of water and agitation to form a suspension ready for use.

39. A method of delivering a fatty delivery agent in a physiologically acceptable medium through a feeding tube to elevate the level of SCFA, the fatty acid delivery agent being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid.

40. The method of claim 39 wherein the physiological acceptable medium is an enteral feed formulation, including,

a) an amino acid source,

b) a carbohydrate source, and

c) a lipid source.

41. The method of claim 39 wherein the fatty acid is a SCFA.

42. The method of claim 41 wherein the carrier is a starch.

43. The method of claim 39 wherein the level of the fatty acid within the large bowel increases within a time period of 6 hrs.

44. The method of claim 39 wherein the level of the SCFA within the large bowel increases within a time period of 4 hrs.

45. The method of claim 39 wherein the level of the fatty acid within the large bowel increases within a time period of 2 hrs.

46. The method of claim 39 wherein the fatty acid delivery agent constitutes less than about 30% by weight of the formulation.

47. The method of claim 39 wherein the fatty acid delivery agent constitutes less than about 20% by weight of the formulation.

48. The method of claim 39 wherein the fatty acid delivery agent constitutes less than about 10% by weight of the formulation.

49. The method of claim 39 wherein the fatty acid delivery agent constitutes less than about 5% by weight of the formulation.

50. A method of delivering a fatty delivery agent in a in an enteral formulation to elevate the level of SCFA within the colon.
the enteral formulation including
a) an amino acid source,
b) a carbohydrate source and
c) a lipid source, and
d) a fatty acid delivery agent being a short chain fatty acid covalently bonded to a starch molecule by a bond hydrolysable in the colon to there by release the fatty acid.

51. The method of claim 50 wherein the enteral formulation is delivered through a nasogastric tube.

52. The method of claim 51 wherein the starch is a resistant starch.

53. The method of claim 52 wherein the resistant starch is a high amylose starch.

54. The method of claim 53 wherein the SCFA is selected from the group consisting of acetate, propionate and butyrate.

55. The method of claim 54 wherein the quantity of fatty acid delivery agent delivered is between 5 and 80gm/day.

56. The method of claim 54 wherein the quantity of fatty acid delivery agent delivered is between about 10 and 60 g/day.

57. The method of claim 54 wherein the quantity of fatty acid delivery agent delivered is between about 40 g/day.

58. The method of claim 55 wherein no more than 2 litres of the enteral formulation is delivered within a 24 hour time period.

59. The method of claim 55 wherein no more than 1 litre of the enteral formulation is delivered within a 24 hour time period.

60. The method of claim 55 wherein the fatty acid delivery agent is present in the formulation between 0.25% and about 5% by weight of the formulation.

61. The method of claim 55 wherein the fatty acid delivery agent is present in the formulation at about 2% by weight of the formulation.

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

PCT/AU 00 / 00792
International Application No.

30 JUN 2000 (30.06.00)
International Filing Date

Australian Patent Office
PCT INTERNATIONAL APPLICATION
Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 1778PCT

Box No. I TITLE OF INVENTION

NASOGASTRIC ENTERAL FORMULATIONS

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Commonwealth Scientific and Industrial
Research Organisation
Limestone Avenue
CAMPBELL ACT 2612
AUSTRALIA

☐ This person is also inventor.

Telephone No. 8303 8869

Facsimile No.

Teleprinter No.

State *(that is, country)* of nationality: Australia

State *(that is, country)* of residence: Australia

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BIRD, Anthony Richard
CSIRO, Human Nutrition
Kintore Avenue
ADELAIDE SA 5000
AUSTRALIA

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: Australia

State *(that is, country)* of residence: Australia

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

A.P.T. Patent and Trade Mark Attorneys
GPO Box 772
ADELAIDE SA 5001
AUSTRALIA

Telephone No. 08 8410 5040

Facsimile No. 08 8410 5042

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

RECORD, Ian Ronald
CSIRO, Human Nutrition
Kintore Avenue
ADELAIDE SA 5000
AUSTRALIA

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: Australia

State *(that is, country)* of residence: Australia

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

TOPPING, David Lloyd
CSIRO, Human Nutrition
Kintore Avenue
ADELAIDE SA 5000
AUSTRALIA

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: Australia

State *(that is, country)* of residence: Australia

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes: at least one must be marked)*:

Regional Patent

- ☒ AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☒ AE United Arab Emirates
- ☒ AL Albania .....
- ☒ AM Armenia .....
- ☒ AT Austria .....
- ☒ AU Australia .....
- ☒ AZ Azerbaijan
- ☒ BA Bosnia and Herzegovina .....
- ☒ BB Barbados
- ☒ BG Bulgaria .....
- ☒ BR Brazil .....
- ☒ BY Belarus .....
- ☒ CA Canada
- ☒ CH and LI Switzerland and Liechtenstein
- ☒ CN China .....
- ☒ CU Cuba .....
- ☒ CZ Czech Republic .....
- ☒ DE Germany .....
- ☒ DK Denmark .....
- ☒ EE Estonia .....
- ☒ ES Spain .....
- ☒ FI Finland .....
- ☒ GB United Kingdom
- ☒ GD Grenada
- ☒ GE Georgia .....
- ☒ GH Ghana .....
- ☒ GM Gambia
- ☒ HR Croatia .....
- ☒ HU Hungary .....
- ☒ ID Indonesia
- ☒ IL Israel .....
- ☒ IN India .....
- ☒ IS Iceland
- ☒ JP Japan .....
- ☒ KE Kenya .....
- ☒ KG Kyrgyzstan .....
- ☒ KP Democratic People's Republic of Korea .....
- ☒ KR Republic of Korea .....
- ☒ KZ Kazakhstan .....
- ☒ LC Saint Lucia
- ☒ LK Sri Lanka
- ☒ LR Liberia
- ☒ LS Lesotho .....
- ☒ LT Lithuania
- ☒ LU Luxembourg
- ☒ LV Latvia
- ☒ MD Republic of Moldova .....
- ☒ MG Madagascar .....
- ☒ MK The former Yugoslav Republic of Macedonia .....
- ☒ MN Mongolia
- ☒ MW Malawi .....
- ☒ MX Mexico .....
- ☒ NO Norway
- ☒ NZ New Zealand .....
- ☒ PL Poland .....
- ☒ PT Portugal .....
- ☒ RO Romania
- ☒ RU Russian Federation .....
- ☒ SD Sudan
- ☒ SE Sweden
- ☒ SG Singapore
- ☒ SI Slovenia .....
- ☒ SK Slovakia .....
- ☒ SL Sierra Leone .....
- ☒ TJ Tajikistan .....
- ☒ TM Turkmenistan .....
- ☒ TR Turkey .....
- ☒ TT Trinidad and Tobago .....
- ☒ UA Ukraine .....
- ☒ UG Uganda .....
- ☒ US United States of America .....
- ☒ UZ Uzbekistan .....
- ☒ VN Viet Nam .....
- ☒ YU Yugoslavia .....
- ☒ ZA South Africa .....
- ☒ ZW Zimbabwe .....

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

- ☒ Costa Rica, Dominica, Morocco
- ☒ Tanzanier, Algeria .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) 1st July 1999	PQ1325	AU		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): (1)

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):* ISA/

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*
Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following number of sheets:

request	:	4
description (excluding sequence listing part)	:	29
claims	:	6
abstract	:	1
drawings	:	3
sequence listing part of description	:	
Total number of sheets	:	43 ✓

This international application is accompanied by the item(s) marked below:

1. ☐ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*:

Figure of the drawings which should accompany the abstract: 4

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

For and on behalf of
Commonwealth Scientific and
Industrial Research
Organisation

Name: JOHN [illegible]
Position: Authorised Officer

Anthony Bird

David Topping

Ian Record

For receiving Office use only

1. Date of actual receipt of the purported international application: 30 JUN 2000 (30.06.00)
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA/
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00792

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.[7]: A61K 47/44, 47/42, 47/36, 47/38, 47/26; A61P 3/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K 47/- AND KEY WORDS AS SET OUT BELOW

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC AS ABOVE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT: FATTY ACIDS, CARBOHYDRATE, STARCH, CELLULOSE, LIPID AND RELATED TERMS.
MEDLINE:

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95/13801 A (COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION), 26 May 1995 page 8 line 8 -page 9 line 32; page 11 line 1-17	1-61
A	EP 451750 A (NB INTERNATIONAL TECHNOLOGIES), 16 October 1991 whole document	1-61
A	US 5723446 A (GRAY et al.) 3 March 1998 Whole document	1-61

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 July 2000	- 8 AUG 2000
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer S. CHEW Telephone No : (02) 6283 2248

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00792

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	9513801	AU	81368/94	CA	2176719	EP	730447
		US	5840860				
EP	451750	AU	74050/91	CA	2039980	JP	5306222
		US	5919822				
US	5723446	NONE					

END OF ANNEX